DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JAN - 7 2002

NADA 141-095

John B Baker
•Associate Director, Regulatory Compliance
Pfizer Inc.
One Pfizer Way
Lee'S Summit, MO 64081
USA

Dear John B Baker,

This is in reference to your Annual Drug Experience Report dated September 14, 2001, concerning Dectomax Pour-On (doramectin), NADA 141-095. This submission includes Clinical Data, Promotional Labeling, and Print Advertisements. In review of your promotional piece entitled: "Dectomax Pour-On Gets Best Results In Weaned Calf Study" DXP0600036, we find the comparative study with Ivermectin to be non-specific and misleading.

The study compares the two products' efficacy against "naturally acquired worm burdens in calves" by measuring fecal egg counts before treatment and at weekly intervals thereafter. Neither the worms nor the fecal eggs are defined by species, host preference, or pathogenicity. This comparison is unfair and misleading in light of the fact that the two products are approved for different parasite species. In addition, the non-treated group at day --1 began with an average fecal egg count at almost twice the amount of eggs as the Dectomax Pour-On group (409.0 vs. 256.7 eggs/gm) while the Ivermectin Pour-On group started with 315.8 eggs/gm. We consider this promotional piece to be biased and misleading in making unfair comparison between the two products.

We have also noted in your Annual Report submission several pieces entitled: "Hell on Lice" or "Licetime Guarantee." Since we had previously addressed this issue in our letter dated January 3, 2000, we did not expect the Lice Guarantee promotion continues to be carried on any longer. We wish to remind you of the commitment you made when you signed the New Animal Drug Application Form FDA 356V that you will promote your product only in accord with the labeling provided for in the approved application.

We request that you immediately discontinue use of the promotional piece cited above and any associated materials that reference the study. Please inform us of your intentions as soon as possible or in any event within 30 days of the receipt of this letter. If you have any questions, you may contact us at (301)827-6642.

Sincerely yours,

Mohammad I. Sharar, DVM, M.Sc.
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and Regulatory Review Team II, HFV-216
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